Cover Page

Title of study: A wrist biosensor-based mHealth suite to support alcohol intervention in young people living with HIV (SHARE Engage)

NCT05431855

Informed Consent Form

Approved by sIRB Florida State University September 4, 2024

Permission to Take Part in a Human Research Study

Title of research study: A wrist biosensor-based mHealth suite to support alcohol intervention in young people living with HIV

Investigator: Sylvie Naar, PhD; Yan Wang, PhD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you are between 18 and 29 years of age, currently reside in Florida, are HIV positive, report having had at least 1 alcoholic drink in the last 30 days, are able to read and understand English, have access to the internet via smartphone, tablet, or computer, and are not pregnant.

What should I know about a research study?

- The research team will be available to answer any questions you may have about this form.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The main goal of this study is to develop a mHealth suite based on a wrist alcohol biosensor (BACtrack Skyn) to help self-management of alcohol use among young people living with HIV (YPLWH).

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 2 months. If you choose to enroll in this study you will be asked to:

1. Complete a set of online surveys upon enrolling and at the 1-month follow-up
2. Provide HIV viral load (VL) results that are no later than 1 month from your follow-up assessment in this study; if you do not have recent VL results, there are other options if you still want to participate: (1) provide blood specimen (dried blood spots) for HIV VL measurement by requesting a kit from us to be sent via mail, OR (2) sign a release of information form for a clinic to send a copy of your results to the study team.
3. Grant the study team access to your medical information from the Florida Department of Health public health surveillance system.
4. Wear a wrist alcohol biosensor (BACtrack Skyn) for 30 days and report your alcohol use daily using a smartphone app
5. Some will interact with another app that lets you feed and play with virtual animals (up to 60 participants).
6. Provide 1 dried blood spot sample to measure alcohol use after 30 days

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of some questions asked in the online assessments. When scheduling sessions, there is a risk of loss of confidentiality during the calls or text messages. The research team will try to remove identifiers from survey answers and protect your privacy to the best of our ability.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no direct benefits to participants who enroll in this study. However, the results from the current study may inform future research studies and treatment strategies for young people living with HIV.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

- The ENGAGE Project (share-engage@phhp.ufl.edu) (352) 474-8024 (primary contact)
- Yan Wang, PhD. (ywang48@phhp.ufl.edu) (352) 294-5942
- Sylvie Naar, Ph.D. (Sylvie.naar@med.fsu.edu) (248) 207-2903 or
- The SHARE Community Engagement Core team at SHARE.CEC@med.fsu.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 160 people will be in this research study across the state of Florida.

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What happens if I say "yes" to being in this research?

All study procedures will be conducted virtually via Zoom, telephone, text message, or email. You will interact only with study team personnel to minimize any potential risks of breach of confidentiality or other perceived risks. **If you agree to be in the study, you will be asked to complete the following activities:**

1) **Viral Load (VL) Assessment**

   You will be asked to provide results of an HIV viral load obtained no later than 1 month from your follow-up assessment in this study. If you do not have VL results that were obtained within 1 month from your follow-up assessment in this study, you have other options if you still want to participate:

   a) Select (at the end of this form) that you would like us to send you an at-home Dried Blood Spot (DBS) test collection kit*. A member of the study team will contact you to confirm your address to ship a DBS kit to you, OR

   b) You may go to a clinic of your choosing for a VL test and sign a release of information form for the clinic to send the results to the study team.

   ***Dried Blood Spot (DBS) test collection kit -- HemaSpot™ Blood Sampling Kit**: The research team will mail the Spot*On Sciences HemaSpot™ blood sampling kit to the address you provide. This kit includes the HemaSpot™ device, 2 lancets, 2 alcohol pads, 2 sterile gauze pads, and 2 adhesive bandages. The kit also contains printed instructions, as well as a link to an instructional video, from the manufacturer on how to collect and handle your blood with the items provided. The kit requires about 2-3 drops of blood and takes less than 5 minutes to complete. You will then mail the completed kit to Florida State University, Center for Translational Behavioral Sciences, 2010 Levy Avenue, Suite B0266, Tallahassee, FL 32310. The research team will provide you with a mailing kit and pay for the postage. The research team will ask you to complete this process only once after you complete your follow-up assessment; however, the research team may ask you to resubmit another kit in the event there was an error in the collection, handling, and/or mailing of the original kit. The research team will then send the blood specimen to a lab for VL testing.

   If you do not provide VL results that are dated within 1 month after completing the follow up assessment in this study, a member of the study team will contact you to follow-up on VL status and provide you with assistance if needed.

2) **Medical Information from the FDOH Public Health Surveillance System**

   The researchers will also ask for some medical information from the Florida Department of Health up to two years after you complete the study procedures. This may include: 1) your most recent CD4+ T-Cell absolute count before you enrolled in the study; 2) your viral load results for up to a year before you started the study and while you're participating in the study; 3) your ICD-9 codes related to STI diagnoses; 4) information about your HIV care appointments; and 5) your prescribed ART medications while you're in the study.

3) **Baseline and follow-up assessments**

   The researchers will ask you to complete online survey questionnaires at baseline and at 1-month follow up. The survey will include questions such as demographics (e.g., age, gender), alcohol and other substance use, mental health symptoms, other health behaviors, and your opinions on the technologies you use (e.g., phone apps, alcohol biosensor) in this study.

4) **Wearing an alcohol biosensor, completing brief phone surveys, and playing a game over 30 days**

   The researchers will ask you to wear a non-invasive wrist alcohol biosensor (BACtrack Skyn) over a 30-day period. The Skyn biosensor shapes like a fitness track and detects a small amount of alcohol excreted through your skin. The Skyn biosensor has not been FDA-approved to give up-to-date readings for current alcohol levels, as it is only approved for investigational use. As such, the researchers will also ask you to report alcohol use and some related information using a smartphone app (mEMA app) during the 30 days. Lastly, some of the participants will download an app titled "eWrapper Ranch." The eWrapper app is a game that allows you to feed and interact with animals. Up to 60 participants will use the eWrapper app

5) **Provide a dried blood spot sample for testing alcohol use at 1-month follow up**

   The researcher will ask you to provide a dried blood spot (DBS) sample to for testing alcohol use at 1-month follow up. Research staff will mail the DBS collection kit and an illustrated instruction sheet to your preferrable address, with a prepaid pre-addressed envelope for participants to return the sample. The DBS collection kit will be provided by the United States Drug Testing Laboratories (USDTL Inc.), which is a reputable lab for Peth test. The collection kit includes DBS collection supplies (e.g., sterile safety lancet, collection card with five circles for blood drops) and a drying box. You are encouraged to watch a video on YouTube produced by USDTL which walks through the DBS collection process to make sure they perform each step properly. After collection is complete, you will need to mail back the DBS sample to our research team.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

1. Providing viral load results that were obtained within 1 month after your follow-up survey in this study – provide a copy yourself, request a blood specimens (DBS) test collection kit and mail it to the study team, or sign a release waiver for a clinic to send HIV viral load measurement to the study team.
2. Granting the study team permission to request your information from the Florida Department of Health's health surveillance system for up to 1-year prior to study enrollment, and up to 2 years after you complete the baseline activities of this study.
3. Completing the study baseline and 1-month follow-up assessments and the 30-day period, which involved wearing the Skyn sensor, completing brief daily surveys via the mEMA app as described in detail above, and engaging with the eWrapper app (for those randomly chosen to use it).
4. Providing reliable contact information for the study team to communicate with you (e.g. email address), own a mobile phone or device that can receive calls and/or text messages (data rates may apply), and a device (smartphone, tablet, or computer) with access to internet on which you can complete online questionnaires and attend virtual meetings (via Zoom). Zoom meetings will not be recorded or stored.

There will be no direct costs to you for your participation in this research study; there is no direct cost to you for study-related viral load assessments. If you obtain viral load through your medical provider as part of your standard care, the cost of the viral load may be billed to your insurance or other third-

party payer. You may be responsible for any co-pays or deductibles for viral loads measured as part of your standard care. Additional indirect costs may include driving to and from facilities (e.g. health clinic, mailing services).

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you.

It is important that we continue collecting data at the 1-month follow-up assessment. If you decide to withdraw from the study at any point during the study, we ask that you try to inform the study staff of your decision via an email to [SHARE.CEC@med.fsu.edu] so that we stop contacting you for follow-up assessments. If you choose to withdraw, we will ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Information that you provide up to the point of withdrawing may be stored and used later on. You may request that your information be removed and deleted once you withdraw from the study by writing to the researchers via email.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks and discomfort associated with participation in this study do not exceed the risks ordinarily encountered in daily life or self-administered physical tests. This study utilizes the USDTL PEth alcohol blood sampling biomarker for measure of alcohol use as well as the HemaSpot™ blood sampling kit from Spot*On Sciences for those who wish to provide their viral load this way. Spot*On Sciences warns that persons with hemophilia or persons under anti-coagulation therapy (taking blood thinners) should consult their doctor or health care professional prior to using the kit.

In addition, there is some risk of emotional discomfort or distress due to the personal nature of some questions asked in the surveys that you will be asked to complete. If a mental health issue exists prior to the assessments, emotional discomfort or distress may be worse. To reduce the chances of this happening, you may take a break, choose not to respond to specific items, or choose to stop participating if you feel too uncomfortable. Additionally, you may contact the Dr. Sylvie Naar if you would like to talk to someone other than friends or family about your participation.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Florida State University Institutional Review Board, which reviews and monitors research involving human subjects, and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

Confidentiality

Every effort will be made to keep all of the material related to you private and confidential. All your laboratory specimens, questionnaires, evaluation forms, reports, and other records will be identified by a code or participant number. All records with personally-identifying information will be kept in password-protected computers in a locked, limited access area. Clinical information will not be released without your written permission, except as necessary for monitoring by the researchers or the study sponsors.

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Your contact information will be kept confidential – we will only use this information to contact you for the purposes of this study. All personal identifiers will be removed from your survey responses and de-identified responses will be kept indefinitely; your de-identified responses will be saved for future use and may be shared with other researchers.

If you choose to provide a DBS sample, the biological samples collected for the purposes of this study will only be used for analysis and not be used to conduct any future research even if all of your identifiers are removed. Samples will be sent to Brown University analysis and destroyed after analysis is completed.

Certificate of Confidentiality: To help protect your confidentiality, a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Protected Health Information (PHI):

Federal law provides additional protections of your medical records and related health information. Your PHI created or received for the purposes of this study is protected under the federal regulations known as HIPAA. Refer to the HIPAA authorization for details concerning the use of this information.

Linkage to FDOH data: We will ask you to provide your contact information and some other identifying information. With your information we will only do the following: Connect your survey responses to surveillance information that is managed by the Florida Department of Health by providing a list of identifiers.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:

1. During the course of the study, it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If it is determined by the study team that it is in the best interests of your health, and/or
4. If it is determined that you are providing inaccurate or false information.
5. Failing to adhere to the study procedures without communication with the study team

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

Instead of being in this research study, your choices may include not to participate in this research study. Participants always have the option not to participate in this study, and referrals to community-based organizations are available to all study participants.

Results of DBS may be available to you upon request. The research team will not share these results with any other individuals. You may request a written copy be emailed to you as a secure, encrypted email. If you had an undetectable VL, no further steps will be provided. If you have a detectable VL, any necessary referrals will be provided. Upon receiving your VL results, you are encouraged to follow up with your health care provider.

Research Related Injury

There are no funds to pay any costs if you are harmed because of this study. If you think that you were harmed because of this study, let the Principal Investigator know right away, Dr. Sylvie Naar and/or Dr. Yan Wang at sylvie.naar@med.fsu.edu and/or ywang48@phhp.ufl.edu. Make sure you keep this information where you can access it later on. By agreeing to participate in this study, you do not give up your right to seek payment for harm you receive while participating in this study.

Compensation

You may receive up to $240 via CashApp or in the form of a gift card for completing all components of the study. Here is a breakdown of the compensation for each specific component. Upon completion of each component, you will receive:

- $25 for completing the baseline activities
- $10 for providing your Dried Blood Spot PEth specimen
- Up to $10 via the eWrapper app in-game incentives (for those chosen to use the app)
- $50 for completing brief surveys using the mEMA app ($60 if you were not selected to use the eWrapper app)
- Up to $100 bonus if you complete 80% or more mEMA brief surveys each week (see details below)
- $35 for completing the 1-month follow up survey activities
- You may receive an additional $10 if you choose to provide your viral load through a Dried Blood Spot Kit.

If you are not using the eWrapper app, the compensation for the EMA assessments is as follows: Greater than 80% EMA assessment response rate = $60, 60-79% EMA assessment response rate = $50, 50-59% EMA assessment response rate = $40, 40-49% EMA assessment response rate = $30, 20-39% EMA assessment response rate = $20, 0-20% EMA assessment response rate = $10.

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If you are using the eWrapper app, the compensation for the EMA assessments is as follows: Greater than 80% EMA response rate = $50, 60-79% EMA assessment response rate = $40, 50-59% EMA assessment response rate = $30, 40-49% EMA assessment response rate = $25, 20-39% EMA assessment response rate = $20, 0-20% EMA assessment response rate = $10.

There will be bonus for you to complete 80% or more EMA assessments. Bonus will increase each weekly and accumulate to up to $100 total if you complete 80% or more each week on a continuous basis (Week 1: $10, Week 2: $20, Week 3: $30, Week 4: $40). If your completion rate falls below 80%, you will not get bonus that week, and the bonus amount resets at $10 again.

Please note that at the end of the 30-day trial, you will mail back the Skyn biosensor using a pre-paid and pre-labeled box. You will be expected to return your devices as soon as you complete the 30-day study period. If the study devices are damaged or returned more than 2 weeks after you complete the 30-day study period, then $100 will be deducted from your total compensation. The two-week period starts as soon as the research staff inform you that your 30-day period has been completed. Our staff will remind you about when to return the devices. If you don't return the devices (including if you lost either the Skyn sensor and/or the study phone), you will not receive compensation for the 30-day study period activities and follow-up survey (up to $205).

Upon completing each step of the study, you may receive compensation via CashApp or in the form of an electronic gift card. Please select the option that you would prefer:

☐ I would like to receive compensation for completing the study steps via **CashApp only** (CashApp ID will be requested later on)

☐ I would like to receive compensation for completing the study steps in the form of an **electronic gift card only**

☐ I would like to receive compensation for completing the study steps **either via CashApp or an electronic gift card**

Questions to Verify Participant Understands Consent

It is important for the study team to make sure you understand what this study entails. Please answer the following questions:

☐ True or ☐ False:
Participating in the study is my choice and I can choose to stop participating at any time, even if I agree today.

*Correct Answer: **True** – Your participation in this research study is completely up to you. You are allowed to end your participation in the study at any time, whether that is now, ten minutes into the first survey, or a week from now. There is no penalty for stopping your participation.*

☐ True or ☐ False:
Every participant will be asked to provide DBS HIV viral load specimen for the participation of this study.

*Correct answer: **False** –You may provide your viral load in multiple ways, including by providing a copy of viral load documentation provided by your physician via email or through a secure REDCap link, or allowing the study team to contact your health care provider and obtain your HIV viral load from them, and/or by completing an at-home DBS HIV Viral Load test at no cost to you.*

Consent to Be Contacted for Future Research Studies

Would you like to be contacted via email about future studies for which you may be eligible? Your selection will NOT impact your eligibility to enroll in this study.

By Checking "Yes" you are granting permission for the contact and demographic information that you provided to be included in the Scale It Up Florida (SIU) Connect repository so that you may be informed about future research opportunities for which you may be eligible. Your information will be kept secure and confidential by FSU's Center for Translational Behavioral Science. If you no longer wish to be contacted for future studies, you may withdraw your information from the repository at any time by contacting siu.connect@med.fsu.edu. By selecting yes and enrolling in the SIU Connect repository, you are eligible to receive a $5 CashApp payment, and may also be eligible to receive a $20 electronic gift card, as a monthly drawing will provide the gift card to up to 5 enrollees per month. You may be contacted by the SIU study team to confirm your CashApp information, if not already provided as part of enrolling in the SHARE Program. The $5 payment is only available through CashApp, so if you do not have a CashApp account, you will not receive the payment, but will still be eligible for the $20 electronic gift card drawing.

☐ Yes, you may contact me about future research opportunities.

☐ No, you may not contact me about future research opportunities.